REMARKS/ARGUMENTS

Claims 1-66 are pending in this application. Claims 3, 4, 12-55, 58, and 59 are withdrawn from consideration. By this amendment, claims 1 and 56 have been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendment to claims 1 and 56 can be found, *inter alia*, throughout the specification and in particular at page 9, lines 9-11 and page 28, lines 16-17 and 25-27.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejection under 35 U.S.C. §102

Claims 1, 2, 5-11, 56, 57, and 60-66 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schwartz *et al.* (WO 98/55495) ("Schwartz"). Applicants respectfully traverse this rejection.

For a claim to be anticipated by a reference, the reference much teach each and every element of the claim. Claim 1 recites a pharmaceutical composition, comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, comprising: a polynucleotide comprising an immunostimulatory sequence (ISS) linked to the surface of a nonbiodegradable microcarrier (MC), wherein the ISS comprises the sequence 5'-C, G-3', and wherein said microcarrier is less than about 10 μm in size, with the proviso that if the MC is gold, latex or magnetic, the linkage is other than by biotin/avidin; and a pharmaceutically acceptable carrier.

Claim 56 recites a kit, comprising: a container comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, said complex comprising: a polynucleotide comprising an immunostimulatory sequence (ISS) linked to the surface of a microcarrier (MC), wherein said MC is a nonbiodegradable MC and wherein the ISS comprises the sequence 5'-C, G-3', and wherein said microcarrier is less than about 10 μm in size; a pharmaceutically acceptable carrier; and instructions for use of IMP/MC complex in immunomodulation of an individual.

While Schwartz describes various combinations of immunostimulatory polynucleotides with other components, Applicants believe that Schwartz does not identically disclose or describe, within the meaning of 102, the claimed invention.

The Examiner alleges at page 3 of the Office Action that Schwartz teaches pharmaceutical compositions (and kits) comprising an immunomodulatory polynucleotide, which polynucleotide is covalently attached to a non-biodegradable, solid microcarrier between 10nm and 10μm in size. Applicants invite the Examiner's attention to claim 1 and 56 which recite, in part, that the polynucleotide comprises an ISS linked to the surface of a nonbiodegradable microcarrier (MC), wherein the MC is less than about 10μm in size. Applicants invite the Examiner's attention to Schwartz page 15, lines 36-38 which state that the invention provides compositions and methods that comprise an encapsulating agent. Continuing on page 16, lines 1-3 state that the microparticles and/or liposomes encapsulating an ISS-IMM are in the form of particles with the recited sizes. The presently claimed invention recites, in part, that the polynucleotide comprises an ISS linked to the surface of a nonbiodegradable MC that is less than 10 μm in size. In the Office Action mailed November 19, 2003, the Examiner states at page 3 that Schwartz do not teach non-encapsulated polynucleotide/microcarrier complexes, nor covalently linked polynucleotide/microcarrier complexes, nor solid phase microcarriers. Each and every element of the claimed invention is not present in Schwartz. Therefore, Schwartz can not, as a matter of law, anticipate the claimed invention.

Claims 1, 2, 5-11, 56, 57, and 60-66 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Raz *et al.* (U.S. Patent No. 6,589,940) ("Raz"). Applicants respectfully traverse this rejection.

Applicants believe that Raz does not identically disclose or describe, within the meaning of 102, the claimed invention. Raz has no specific disclosure or description of a pharmaceutical composition, comprising: an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, comprising: a polynucleotide comprising an immunostimulatory sequence (ISS) linked to the surface of a nonbiodegradable microcarrier (MC), wherein the ISS comprises the sequence 5'-C, G-3', and wherein said microcarrier is less than about 10 μm in size, with the proviso that if the MC is gold, latex or magnetic, the linkage is other than by biotin/avidin, and a pharmaceutically acceptable carrier, kits comprising such complexes or methods of using them. While Raz at col. 14 describes that adjuvants include microparticles, Raz does not disclose or describe that the ISS is linked to the surface of a nonbiodegradable MC, wherein said MC is less than 10 μm in size. Applicants invite the Examiner's attention to col. 16, lines 42-46 which state that the invention provides compositions and methods of use comprising an encapsulating agent. Continuing at col. 16, lines 49-54 state that the microparticles and/or liposomes encapsulating an ISS-IMM are in the form of particles with the recited sizes. The presently claimed invention recites, in part, that the polynucleotide comprises an ISS linked to the surface of a nonbiodegradable MC that is less than 10 μm in size. Each and every element of the claimed invention is not present in Raz. Therefore, Raz can not, as a matter of law, anticipate the claimed invention.

Claims 1, 2, 5-9, 56, 57, and 60-64 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Schwartz (U.S. Pat. No. 6,562,798, "Schwartz '798"). Applicants respectfully traverse this rejection.

Applicants believe that Schwartz '798 does not identically disclose or describe, within the meaning of 102, the claimed invention. Schwartz '798 has no specific disclosure or description of a pharmaceutical composition, comprising: an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, comprising: a polynucleotide comprising an immunostimulatory sequence (ISS) linked to the surface of a nonbiodegradable microcarrier (MC), wherein the ISS comprises the sequence 5'-C, G-3', and wherein said microcarrier is less than about 10 μm in size, with the proviso that if the MC is gold, latex or magnetic, the linkage is other than by biotin/avidin, and a

pharmaceutically acceptable carrier, kits comprising such complexes or methods of using them. The Examiner states at page 4 of the Office Action that Schwartz '798 teach pharmaceutical compositions (and kits) comprising an immunomodulatory polynucleotide which comprises and ISS sequence which polynucleotide is attached to a non-biodegradable, solid MC between 10nm and 10μm in size. Schwartz '798 teach immunomodulatory compositions comprising an ISS in which at least one base has been substituted with a base modified by the addition to C-5 and/or C-6 on cytosine with an electron-withdrawing group. See Schwartz '798 col. 1, lines 19-25. While Schwartz '798 describes at col. 9, lines 52-67 that adjuvants include microparticles, Schwartz '798 does not disclose or describe that the ISS is linked to the surface of a nonbiodegradable MC, wherein said MC is less than 10 μm in size. Schwartz '798 at col. 13, lines 18-36 states that the invention provides compositions and methods of use comprising an encapsulating agent and further that the microparticles and/or liposomes encapsulating a modified ISS are in the form of particles having the recited sizes. The presently claimed invention recites that the ISS is linked to the surface of a nonbiodegradable MC, wherein said MC is less than 10 μm in size. Each and every element of the claimed invention is not present in Schwartz '798. Therefore, Schwartz '798 can not, as a matter of law, anticipate the claimed invention.

Applicants respectfully request reconsideration and withdrawal of all the rejections under 35 U.S.C. §102.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882001700. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By 

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